

REMARKS

OBJECTION TO THE TITLE OF THE INVENTION (Paragraph 2 of Office Action)

The title of the invention has been objected to by the Examiner because it is not descriptive. In order to advance prosecution, Applicants have amended the title to read --A Stable Ointment Containing Acetylsalicylic Acid--. In view of the amendment to the title, reconsideration and withdrawal of the objection to the title are requested.

REJECTION OF CLAIMS 1, 2, 8, 9 AND 14-15 UNDER 35 U.S.C. 112 (Paragraph 3 of Office Action)

Claims 1, 2, 8, 9 and 14-15 have been rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth in paragraph 3 of the Office Action. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner rejects claims 1, 2, 8, 9, 14 and 15 because of the use of the trademark "Vaseline". In order to expedite prosecution, Applicants have substituted the term "petrolatum" for the term "Vaseline". This is clearly a non-narrowing claim amendment. Support for the term "petrolatum" is found on page 1, line 11 of the specification.

The Examiner rejects claims 1, 7 and 14 because of the phrases "substantially anhydrous" and "the ointment does not contain water" in the same claim. Unfortunately, the Examiner misstates the limitations that he is rejecting. However, in order to advance prosecution, Applicants have deleted the phrase "substantially anhydrous" from the claims in favor of the limitation "wherein the ointment does not contain water for dissolving said acetylsalicylic acid." Water may be present in the present claim (i.e. substantially anhydrous). However, the amount of water is clearly limited. That is, the ointment must not contain an amount of water that will dissolve acetylsalicylic acid. This clarification should clearly overcome the rejection under 35 U.S.C. 112, second paragraph.

In view of the amendments to the claims and the remarks hereinabove, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, second paragraph, are respectfully requested.

REJECTION OF CLAIMS 1-6, 8-10 AND 14-15 UNDER 35 U.S.C. 102(a)/102(b) (Paragraphs 4 and 5 of Office Action)

Claims 1-6, 8-10 and 14-15 have been rejected by the Examiner under 35 U.S.C. 102(a)/102(b) for the reasons set forth in paragraphs 4 and 5 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

At the outset, the Examiner is respectfully requested to clarify the basis for the rejection (i.e. 35 U.S.C. 102(a) and/or 102(b)).

Claims 15 and 16 exclude water in any amount. Thus, it is not clear why the Examiner is focusing on water in the prior art section of the Office Action. The Examiner's position is that the claims do not exclude water because they recite "substantially anhydrous ointment". The Examiner should note that claim 15 is directed to an anhydrous ointment rather than to a substantially anhydrous ointment. However, the Examiner clearly has not addressed or apparently even noticed this distinction. Also note that claim 15 recites that the ointment must not contain an amount of water that will dissolve acetylsalicylic acid. Clarification of the Examiner's position is requested.

Indeed, all of the claims recite the limitation that the ointment must not contain an amount of water that will dissolve acetylsalicylic acid. However, the Examiner nowhere addresses this limitation. Rather, the Examiner focuses on the lack of equivalency between "substantially anhydrous" and "anhydrous". This is a false issue as Applicants have never alleged that these terms are equivalent. Indeed, one of ordinary skill in the art should recognize the differences between these terms. However, in order to reduce issues at this stage, Applicants have simply removed the

phrase "substantially anhydrous" from the claims. The Examiner is therefore again requested to explain how the prior art teaches compositions having the claimed limitation that the ointment must not contain an amount of water that will dissolve acetylsalicylic acid.

In the JP 3-72426 reference cited in the Office Action, the subject matter of the present claims 1-6, 8, 14 and 15 is not disclosed. As discussed in the response (pages 5-6) filed on July 5, 2001, an aspirin solvent such as diethylene glycol monoethyl ether, etc. is essential in the compositions of the reference (See English translation of JP 3-72426 (page 5, lines 6-10)). In addition, the compositions in all of the Working Examples in the reference contain such an aspirin solvent.

With respect to Comparative Example 1 in the cited reference, a composition consisting of aspirin, polysorbate 80 and plastibase is used. However, nowhere in the reference is the subject matter of the present claims 1-6, 8, 14 and 15 disclosed. That is, there is no disclosure of an ointment of aspirin, and hydrocarbon gel and/or vaseline.

The composition directed to the present invention is not a composition of vaseline and/or hydrocarbon gel. Rather, the invention is a composition of aspirin, vaseline and/or hydrocarbon gel. On the other hand, the reference may disclose a composition

consisting of vaseline and/or hydrocarbon gel as the ointment base composition as mentioned in the reference from page 4, line 11 to page 5, line 5. However, a composition of aspirin and vaseline and/or hydrocarbon gel is nowhere disclosed in the cited reference.

The cited reference relates to a composition containing at least aspirin, one aspirin solvent and one ointment base. The composition containing aspirin of present invention does not use an aspirin solvent. Therefore, it is impossible for one of ordinary skill in the art to expect that the present invention can maintain the stability of aspirin without any aspirin solvent for long term.

The Examiner should note that the cited reference was filed by the assignee of the present patent application. Nevertheless, at that time the assignee as well as one of ordinary skill in the art would not have obtained the present invention, namely a composition that can maintain the stability of aspirin without any aspirin solvent over the long term.

As discussed in the present patent specification (page 4, lines 1-3), after melting a base (namely vaseline, hydrocarbon gel or a mixture thereof) by warming, thereto fine powders of aspirin are added under stirring and mixed to prepare ointments (e.g. the compositions of the present invention).

Therefore, the Examiner's opinion that the cited reference identically discloses each and every element of the present claims is clearly wrong and the rejection should be withdrawn.

Finally, the present invention is clearly superior to the invention disclosed in the reference because the present invention does not require any aspirin solvent. The present invention is different from the subject matter disclosed in the cited reference. Accordingly, the Examiner is requested to explain how the cited reference anticipates or suggests the present invention.

In view of the amendments to the claims and the remarks hereinabove, the rejection of claims 1-6, 8-10 and 14-15 under 35 U.S.C. 102(a)/102(b) should be withdrawn by the Examiner.

#### **REQUEST FOR AN INTERVIEW**

Applicants' representative attempted to contact the Examiner in order to schedule an interview. However, the Examiner is no longer at the USPTO. Therefore, the newly assigned Examiner is respectfully requested to grant an interview prior to issuance of any further official communications. Applicants' representative will continue to try to contact the former Examiner's supervisor for the purpose of scheduling an interview.


Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three month extension of time for

filing a response in connection with the present application, and the required fee of \$920.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANCES MADE

IN THE TITLE OF THE INVENTION

Please change the title of the invention from "A Stable Ointment Containing Aspirin" to --A Stable Ointment Containing Acetylsalicylic Acid--.

IN THE CLAIMS

Claims 16-20 have been added.

The claims have been amended as follows:

Claim 1 (Amended) [A substantially anhydrous] An ointment consisting essentially of acetylsalicylic acid and a base selected from the group consisting of hydrocarbon gel, [Vaseline] petrolatum and a mixture thereof without any other additive for said acetylsalicylic acid and wherein the ointment does not contain water for dissolving said acetylsalicylic acid.

Claim 2 (Twice Amended) The ointment of claim 1, wherein the base is hydrocarbon gel or [vaseline] petrolatum.

Claim 8 (Amended) The ointment of claim 1, wherein the base is [vaseline] petrolatum.



Claim 9 (Amended) The ointment of claim 8, wherein the vaseline is selected from the group consisting of white [vaseline] petrolatum and yellow [vaseline] petrolatum.

Claim 14 (Amended) [A substantially anhydrous] An ointment consisting of acetylsalicylic acid and a base selected from the group consisting of hydrocarbon gel, [Vaseline] petrolatum and a mixture thereof without any other additive for said acetylsalicylic acid and wherein the ointment does not contain water for dissolving said acetylsalicylic acid.

Claim 15 (Amended) An anhydrous ointment consisting essentially of acetylsalicylic acid and a base selected from the group consisting of hydrocarbon gel, [Vaseline] petrolatum and a mixture thereof without any other additive for said acetylsalicylic acid and wherein the ointment does not contain water for dissolving said acetylsalicylic acid.